[0034] The inventors have also surprisingly and unexpectedly found that a dammarance sapogenin structure which is free of a hydroxyl at C-20, even though there may be a sugar moiety on the structure, demonstrates effective anti-cancer activity, particularly in the treatment of multi-drug resistant cancers. PAN-20 and PAN-30, according to this invention, fall into this latter category.

[0035] While the inventors do not wish to be bound by any adverse theories if proved to be unfounded, the inventors offer the following as an aid in understanding the invention. It seems that sapogenins that have no hydroxyl at C-20 compared to sapogenins that have a hydroxyl at C-20 are surprisingly effective in cancer treatment. It also seems that a sapogenin that does not have a sugar moiety (glycon) on the sapogenin structure, is more effective than sapogenins that include a sugar moiety. It also seems that the diol is more effective than the triol. None of this could be predicted, or forecast without testing the sapogenins of the invention.

[0036] According to this invention and varying with the severity of symptoms experienced by the patient, the active daily dose of sapogenin PAM-120 is 0.1 mg – 10 g per kg of body weight, or preferably, 1mg – 1 g per kg of body weight. The active daily dose of sapogenin PBM-110 is 0.1 mg – 10 g per kg of body weight, or preferably, 1mg – 1 g per kg of body weight. The active daily dose of sapogenin PBM-100 is 0.1 mg – 10 g per kg of body weight, or preferably, 1mg – 1 g per kg of body weight. The active daily dose of sapogenin PAN-20 is 0.1 mg – 10 g per kg of body weight, or preferably, 1mg – 1 g per kg of body weight. The active daily dose of sapogenin PAN-30 is 0.1 mg – 10 g per kg of body weight, or preferably, 1mg – 1 g per kg of body weight.

[0037] The anti-cancer agent according to this invention contains one or more of the said novel sapogenins PAM-120, PBM-100, PBM-110, PAN-20 and PAN-30, with or without other anti-cancer agent, used with or without one or more pharmaceutically acceptable carriers such as solid and liquid excipients.

[0038] The administration forms of the said anti-cancer agents according to the invention are listed as follows:

- Injection forms, including but not limited to intramuscular (IM) injection, intravenous (IV) injection, subcutaneous injection and targeted-tissue injection in aqueous solutions, oil solutions, emulsion, or any forms;

- Oral forms, including but not limited to tablets, capsules, granules, pills, suspensions, powders, sprits, emulsifiers, and syrups; and
- Topical form, including but not limited to drops, lotions, enemas, ointments, suspensions, paps, pastes, suppositories, aerosols, cataplasmas, emulsifiers, liniments, and plasters.

[0039] This invention also relates to a production process that can be used to commercially produce the above mentioned novel dammarane sapogenins for anti-cancer applications through chemical cleavage and semi-synthesis of dammarane saponins.

[0040] Figure 7 illustrates a flow sheet of two alternative processes which can be utilized to produce the sapogenins according to the invention. The production process according to the invention uses general ginsenosides (also called dammarane saponins including Ra, Rc, Rd, Re, etc.) extracted from plants selected from the ginseng family such as panax ginseng, panax quinguefol and panax notoginseng as raw materials. In the process, according to this invention, general ginsenosides are first mixed with water and then with short-chain (1-5 carbon) alkali-metal alcoholate solution or hydroxide-ethanol solution. The mixture is then put into a reaction tank to undergo chemical reactions under required high temperature and high pressure. Alternatively, general ginsenosides are first mixed with ethanol, and then with alkali-metal alcoholates solution. The mixture is thereafter put into a reaction tank to undergo chemical reactions under required high temperature and high pressure. After the required period of time for the reaction to be complete, the intermediate product of a mix of ginsenosides and sapogenins are collected from the ethanol solution. The next step is to separate the desired dammarane sapogenins from the intermediate saponin-sapogenin mix by using silica-gel-column chromatography. According to this invention, the said alkali metal can be potassium or sodium, the hydroxide can be sodium hydroxide or potassium hydroxide, the concentration of alkali-metal alcoholates solution or the concentration of hydroxide-ethanol solution can be 5~50% (W/V), and the short chain alcohol can be one with 1~5 carbon atoms. In this invention, during the production process, the reaction tank's temperature can be between 150~300°C and the reaction pressure is between 2.5~8.4 MPa.

[0041] Cancers susceptible to treatment with the compounds of the invention alone or in combination with a chemotherapeutic in accordance with various aspects of the

invention may include both primary and metastatic tumors and hyperplasias, including carcinomas of breast, colon, rectum, lung, oropharynx, hypopharynx, esophagus, stomach, pancreas, liver, gallbladder and bile ducts, small intestine, urinary tract (including kidney, bladder and urothelium), female genital tract (including cervix, uterus, and ovaries as well as choricarcinoma and gestational trophoblastic disease)), male genital tract (including prostate, seminal vesicles, testes and germ cell tumors), endocrine glands (including the thyroid, adrenal, and pituitary glands), and skin, as well as hemangiomas, melanomas, sarcomas (including those arising from bone and soft tissues as well as Kaposi's sarcoma), and tumors of the brain, nerves, eyes, and meninges (including astrocytomas, gliomas, glioblastomas, retinoblastomas, neuromas, neuroblastomas, Schwannomas, and meningiomas). In some aspects of the invention, the compounds of the invention in combination with a chemotherapeutic may also be useful in treating hematopoietic cancers such as leukemias (i.e. chloromas, plasmacytomas and the plaques and tumors of mycosis fungoides and cutaneous T-cell lymphoma/leukemia) and lymphomas (both Hodgkin's and non-Hodgkin's lymphomas).

[0042] The compounds of the invention and the chemotherapeutic may be administered in combination separately or as one single combined pharmaceutical composition. The amount of each component administered may be determined by an attending clinician, taking into consideration a variety of factors such as the etiology and severity of the disease, the patient's condition and age and the potency of each component. the components may be administered in accordance with the standard methodologies as, for example, disclosed in the Physician's Desk Reference (PDR) published by Medical Economics Co. Inc. of Oradell, N.J.

[0043] One or more pharmaceutically acceptable carriers or exipients may be used to formulate pharmaceutical compositions of the invention, including solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like that are physiologically compatible. In alternative embodiments, the carrier may be suitable for parenteral, intravenous, intraperitoneal, intramuscular, sublingual or oral administration. Pharmaceutically acceptable carriers may include sterile aqueous solutions or dispersions and sterile powders for the extemporaneous preparation of sterile injectable solutions or dispersion. Except insofar as any conventional media or agent is incompatible with the active compound, use thereof in the pharmaceutical compositions of the invention is contemplated. Supplementary active compounds can also be